MAY 15 2008

510(k) Summary of Safety and Effectiveness for Genzyme Cystatin C

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K080662

1. **Manufacturer's Name, Address, Telephone, Contact, Date of Preparation:**

Manufacturer:	Genzyme Corporation Genzyme Diagnostics 31 New York Avenue Framingham, MA 01701
Contact Information:	Genzyme Corporation 31 New York Avenue Framingham, MA 01701 Attn: Eric Lawson Tel: 800.332.1042
Preparation date:	March 6, 2008

2. **Device Name / Classification:**

Trade or Proprietary Name:	Genzyme Cystatin C Reagent Genzyme Cystatin C Calibrator
Common or Usual Name:	Test, Cystatin C Calibrator for Cystatin C test
Classification Name:	Creatinine Test System Calibrator, Secondary

3. **Identification of the Legally Marketed Device:**
   Dade Behring N Latex Cystatin C - k041878
   Dade Behring N Protein Standard UY, calibrator - k003501

4. **Device Description:**
   Genzyme Cystatin C assay reagent is based on the sol particle turbidimetric immunoassay principle. It contains colloidal gold particles coated with anti-cystatin C specific polyclonal antibodies. The reaction between the particles and any cystatin C in samples results in the formation of agglutinates and an associated change in absorbance signal. The change in absorbance signal is proportional to the amount of cystatin C in the sample. Cystatin C concentration in the sample is determined by comparison with a standard curve.

Genzyme Cystatin C calibrators consist of a bovine serum albumin liquid matrix with assigned concentrations of cystatin C. The calibrators are preserved with sodium azide and are ready to use.

5. Device Intended Use:

Reagents:

The Genzyme Cystatin C assay reagent is an *in vitro* diagnostic test intended for the quantitative measurement of cystatin C concentration in human serum, heparinized plasma and EDTA plasma. Cystatin C measurements are used as an aid to the diagnosis and treatment of renal diseases.
For In Vitro Diagnostic Use.

Calibrator:

Genzyme Cystatin C calibrator is an *in vitro* diagnostic product for the calibration of Genzyme Cystatin C assay.
For In Vitro Diagnostic Use.

6. Medical device to which equivalence is claimed and comparison information:

The Genzyme Cystatin C diagnostic test is substantially equivalent to the Dade Behring, Inc. N Latex Cystatin C method (k041878) with respect to the indications for use, the analyte tested, device design, the type of antibody materials, and the general sample matrix. The basic differences between the new device and the predicate are the assay technology and the instruments used for testing. The Genzyme device is a turbidimetric immunoassay that can be used on commercially available clinical analyzers using light absorption detection systems; while, the Dade Behring test is an immunonephelometric assay applicable only on Dade Behring, Inc. Nephelometer Systems.
The Genzyme Cystatin C calibrator is substantially equivalent to the Dade Behring N Protein Standard UY calibrator (k003501) with regard to the technological characteristics and in terms of the intended use. The difference is that the Genzyme calibrator is provided as a set of six liquid solutions of assigned cystatin C concentration levels and is ready to use for calibration; while, the Dade Behring N Protein Standard UY is a single lyophilized concentration of cystatin C calibrator that is prepared to various levels in order to establish values for calibration.

7. Device Performance Characteristics:

Performance characteristics and data from nonclinical tests submitted in the premarket notification submission support a determination of substantial equivalence of the Genzyme Cystatin C devices with the Dade Behring predicate devices. This testing includes: analytical limits and sensitivity, within run and total precision testing over 20 days, linearity, reportable range, stability, analytical specificity, interfering substances, matrix comparison, and reference range. Method comparison studies performed with clinical

specimens demonstrate comparable performance and accuracy, good correlation, and substantial equivalence.

8. Conclusion:

In conclusion, the new devices Genzyme Cystatin C Reagent and Genzyme Cystatin C Calibrator, do not raise any new issues of safety or effectiveness, and are substantially equivalent to the currently marketed Dade Behring devices N Latex Cystatin C test kit (k041878), and N Protein Standard UY calibrator (k003501) respectively, as demonstrated by the descriptions and performance data acquired by Genzyme and summarized in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Genzyme Corporation
c/o Mr. Eric Lawson
Manger, Biomedical Regulatory Affairs
31 New York Avenue
Framingham, MA 01701

MAY 15 2008

Re: K080662
Trade/Device Name: Genzyme Cystatin C Reagent and Calibrator
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: NDY and JIT
Dated: March 06, 2008
Received: March 10, 2008

Dear Mr. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K080662

Device Name: Genzyme Cystatin C Reagent
Genzyme Cystatin C Calibrator

Indication For Use:

Reagents:
For the quantitative measurement of cystatin C concentration in human serum, heparinized plasma and EDTA plasma. Cystatin C measurements are used as an aid to the diagnosis and treatment of renal diseases.
For In Vitro Diagnostic Use.

Calibrator:
For the calibration of Genzyme Cystatin C assay.
For In Vitro Diagnostic Use.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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